UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,946	05/02/2001	Michael J. May	PPI-119	6173

959 7590 10/05/2004

LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,946	MAY ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on July 15, 2004. Claims 1, and 2 have been cancelled. Claims 3-13 are currently pending and are under examination.

Withdrawal of Rejections

2. The provisional rejection of claims 3-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-25, and 35 of copending Application No. 09/847,940 is withdrawn, based on the Amendment in copending Application No. 09/847,940 cancelling claims 16-25, and 35.

3. The rejection of claims 11, and 13 under 35 U.S.C. § 112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, due to method of disclosing amino acid sequences with a sequence identifier (SEQ ID NO:) is withdrawn.

4. The rejection of claims 3-10, 12, and 13 under 35 U.S.C. § 102(e) as being anticipated by May et al. (WO 01/83554) is withdrawn.

5. The rejection of claims 3-13 under 35 U.S.C. § 103(a) as being unpatentable over May et al. (WO 01/83554) is withdrawn.

Maintenance of Objections and Rejections

Claim Objections

6. Claims 3, 6, 11, 12, and 13 are objected to because of the following informalities:

The sequences disclosed are not in compliance with 37 CFR 1.821-1.825. Specifically see 37 CFR 1.822(d) 1. The amino acids in a protein or peptide sequence shall be listed

using the three-letter abbreviation with the first letter as an upper case character, as WIPO Standard ST.25 (1998), Appendix 2, Table 3.

Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of copending Application Nn. 09/643,260. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 19-21 in U.S. Patent Application 09/643,260 are directed to SEQ ID NO:2, which comprises Leu-Asp-Trp-Ser-Trp-Leu (current application, SEQ ID NO:33, claim 6).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3-5, and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. A sequence identifier (SEQ ID NO.) is required for any amino acid sequence greater than 4 amino acids in length. In claims 3, and 7-10, the variable X_a, which is a membrane translocation domain is undefined?

12. It is unclear how X_a can be 6 to 15 amino acids in claim 3, and be the amino acid sequence TA in claim 4?

13. In Claim 5, it is still not clear where the additional amino acids are part of the claimed anti-inflammatory compound?

14. Claim 11 is rejected for depending on a rejected claim.

Response to Applicant's Remarks

Applicant states beginning on page 16 of the remarks that the claimed anti-inflammatory compound is sufficiently clear and definite in view of the Applicant's specification such that one of ordinary skill in the art would understand the scope and use of the presently claimed invention. Applicant states the variable X_a is explicitly defined in the specification at page 18, lines 24 through 34. Applicant states the function of variable X_a is also explicitly defined at page 12, beginning on line 19 as "a peptide capable of permeating the membrane of a cell and which is used to transport attached peptides into a cell *in vivo*." Applicant states that if the claims, read in light of the specification reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. § 112, second paragraph) demand no more.

Applicant is referred to MPEP 2111, Claims must be given their broadest reasonable interpretation. Reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is quite a different thing from reading limitations of the specification into a claim, to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothe et al. (WO 99/01541, Publication date=January 14, 1999). Rothe et al. teach SEQ ID NO: 2 comprising: TALDWSWLQTE at amino acid residues 735-745. Therefore, Rothe et al. teach compounds comprising TALDWSWLQTE, LDWSWLQTE, TALDWSWL, ALDWSWLQTE, LDWSWLQTE, LDWSWL, TALDWSWLQT, TALDWSWLQ, ALDWSWLQT, LDWSWLQ, and LDWSWLQT. In SEQ ID NO: 4, LDWSWL is taught at amino acid residues 738-743, and peptides comprising the sequence are taught on page 4, line 9 as residues 737-745. Therefore, Rothe et al teach compounds comprising LDWSWL.

Response to Applicant's Remarks

Applicant states beginning on page 19 of the remarks that the claimed anti-inflammatory compound is not anticipated by the amino acid sequence disclosed by Rothe et al. Applicants

state in the remark on page 20 that Rothe et al. disclose an amino acid sequences TALDWSWLQTE and LDWSWLSEQ. However, Rothe et al. do not teach or suggest the present claimed element of fusing these peptide sequences to a membrane transduction domain, let alone the particular domain recited in claims 3-10. Therefore, Rothe et al. do not anticipate the presently claimed invention.

The amino acid sequence described Rothe et al. inherently possesses the functional qualities of the anticipated fusion protein. Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility.** (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can,* state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing. Applicants state that Rothe et al. has disclosed amino acid sequences, TALDWSWLQTE, and LDWSWLSEQ, which is currently encompassed by the formula of claim 3. It is recognized by a person of ordinary skill in the art that a disclosed protein structure will always produce a function based on structure. Therefore the amino acid sequence does anticipate claims 3-10.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothe et al. (January 14, 1999; WO 99/01541), in view of Applicants admissions in the election response filed December 1, 2003. The teachings of Rothe et al. are set forth above. Applicants state that that the peptides encompassed by the claims clearly represent a single invention in that they are connected in design, operation, and effect, i.e., are not independent inventions. Therefore, in view of Applicants admissions, all claimed peptides are rendered obvious over the teachings of Rothe et al.

Response to Applicant's Remarks

Applicant states on page 21 of the remarks that the claimed anti-inflammatory compound is not rendered obvious by the amino acid sequence disclosed by Rothe et al. Applicants state in

the remark on page 21 that Rothe et al. disclose an amino acid sequences TALDWSWLQTE and LDWSWLSEQ, but Rothe et al. do not teach or suggest the present claimed element of fusing these peptide sequences to a membrane transduction domain, let alone the particular domain claimed by Applicant. Therefore, the examiner has failed to establish a prima facie case of obviousness.

Applicants also argue that the peptides encompassed by the claims can represent a single invention because they are connected in design, operation, and effect, but that a single invention is in no way equivalent to an admission that the peptides of the present invention are collectively obvious over a prior art reference. This is not found persuasive, either the peptides are a single invention and any peptide encompassed by design, operation, and effect, would be obvious one over the other, or the peptides would encompass different inventions.

New rejection

19. Claims 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothe et al. (January 14, 1999; WO 99/01541), in view of Schwarze et al. (Science Vol. 285, pp. 1569-1572 (1999)). The teachings of Rothe et al. are set forth above. Schwarze et al. discloses efficient delivery of therapeutic compounds into cells using the amino terminal 11 amino acid protein transduction domain from human immunodeficiency virus TAT protein, which is the first 11 amino acids of SEQ ID NO: 133 disclosed in claim 12 (see entire document, particularly 2nd paragraph of Introduction, and the sequence disclosed in reference 7). One would have been motivated to fuse the amino acid sequence disclosed by Rothe et al. with the transduction domain disclosed by Schwarze et al. to increase transduction of the therapeutic peptide into a cell. It would have been obvious to a person having ordinary skill in the art to fuse the amino acid

sequence disclosed by Rothe et al. with the protein transduction domain disclosed by Schwarze et al. to deliver the therapeutic peptide compound into cells (current application, claims 3-13).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson PhD

September 28, 2004

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER